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Attorney Docket No. MED-04703/29

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF APPEALS AND INTERFERENCES**

In re application of: Morris et al.

Serial No.: 09/954,759

Group No.: 3764

Filed: Sept. 18, 2001

Examiner: D. DeMille

For: PORTABLE, SELF-CONTAINED APPARATUS FOR DEEP VEIN THROMBOSIS
(DVT) PROPHYLAXIS

APPEAL BRIEF

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Commissioner for Patents
PO 1450
Alexandria, VA 22313-1450

Dear Sir:

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I. Real Party in Interest.

The real party in interest is MedIdea, LLC, a Michigan Limited Liability Company.

II. Related Appeals and Interferences.

There are no other related appeals or interferences.

III. Status of Claims.

Claims 1-20 were canceled upon filing the present application as a continuation application.

Claims 21-50 were added in Preliminary Amendment, and all are under appeal.

IV. Status of the Amendments.

No after-final amendments have been made.

V. Summary of the Invention.

The subject invention improves upon the prior-art by providing an entirely self-contained, patient-worn apparatus for deep vein thrombosis (DVT) prophylaxis, and related conditions. According to a preferred embodiment, an inflatable/deflatable bladder is disposed against an extremity such as the upper calf, foot or within a cast (Specification, page 3, lines 19-24). To treat edema, an inflatable/deflatable bladder may be disposed against at least a portion of the hand. A generally inelastic member is preferably used to fully enclose the bladder and associated body part, such that compressive forces are directed substantially entirely against the body part of the patient when the bladder expands, thereby conserving the power and reducing the volume of pneumatic compression required to operate the device (Specification, page 3, line 24 to page 4, line 8). Given this conservation of energy, the invention may be battery operated from a source immediately proximate to the bladder arrangement, enabling the entire device to be self-contained and, in fact, worn by the patient. The reduced volume also allows the use of miniaturized components including the compressor motor and compressor (Specification, page 4, lines 8-13).

The miniature pump is preferably capable of inflating the bladder to a desired level of pressure so as to augment venous return (Specification, page 4, lines 14-16). A valve may be provided as a pressure release mechanism or, preferably, a natural bleeding of the system is relied upon for decompression following an inflation cycle (Specification, page 4, lines 16-19). The electronics used to drive the compressor, which may be of the type used in commercial blood-pressure measurement cuffs, may be very simple, including a solid-state timer coupled to a relay or other appropriate switching means (Specification, page 4, lines 19-22).

A distinct advantage of the invention is that the device may be worn at all times, including the limb being operated upon during surgery (Specification, page 4, lines 23-25). In an alternative embodiment, to further increase battery life, a sensor may be provided to detect movement of the limb (from which muscle contractions may be implied), such that, should the patient be walking or otherwise active, the pumping action is terminated. One or more mercury switches or other appropriate movement sensors may be utilized for such purpose (Specification, page 4, line 25 to page 5, line 6).

The inventive apparatus may additionally be programmed to decrease the rate of inflation/deflation as a function of time, since it is known that the patient is most vulnerable during and

immediately after surgery. Thus, the inventive apparatus may automatically be programmed to facilitate a relatively high inflation/deflation rate during a surgical procedure, but then taper off to a more infrequent cycling as a function of time (Specification, page 5, lines 7-14).

VI. Issues on Appeal.

1. Are claims 21-28, 32-34 and 37-50 unpatentable under 35 U.S.C. §103(a) over Taheri, U.S. Patent No. 4,941,458?
2. Are claims 29 and 30 unpatentable under 35 U.S.C. §103(a) over Taheri, U.S. Patent No. 4,941,458, in view of Tumey, U.S. Patent No. 5,769,801?
3. Is claim 31 unpatentable under 35 U.S.C. §103(a) over Taheri, U.S. Patent No. 4,941,458, in view of Vinmont, U.S. Patent No. 3,908,642?
4. Is claim 35 unpatentable under 35 U.S.C. §103(a) over Taheri, U.S. Patent No. 4,941,458, in view of Corcoran, U.S. Patent No. 2,880,721?
5. Is claim 36 unpatentable under 35 U.S.C. §103(a) over Taheri, U.S. Patent No. 4,941,458, in view of Johnson, Jr. et al., U.S. Patent No. 5,496,262?

VII. Grouping of the Claims.

Appellant believes the following groups of claims represent patentably distinct inventions which should be given independent consideration on appeal:

- Group I - Claims 21, 32-34 and 37, which stand or fall together;
- Group II - Claims 22, 43 and 45, which stand or fall together;
- Group III - Claims 23, 44 and 48, which stand or fall together;
- Group IV - Claims 24, 38, 46 and 49, which stand or fall together;
- Group V - Claims 25 and 39, which stand or fall together;
- Group VI - Claims 26 and 40, which stand or fall together;
- Group VII - Claims 27 and 41, which stand or fall together;
- Group VIII - Claims 28, 42, 47 and 50, which stand or fall together;
- Group IX - Claims 29-30, which stand or fall together;
- Group X - Claim 31;
- Group XI - Claim 35; and

Group XII - Claim 36.**VIII. Argument.**Group I - Claims 21, 32-34 and 37, which stand or fall together

The claims of this group stand rejected under 35 U.S.C. §103(a) over Taheri et al., U.S. Patent No. 4,941,458. Taheri teaches a device for aiding cardiocepital venous flow from the foot and leg of a patient. The disclosed device includes a first flexible fabric cuff for encircling the arch and instep of a patient's foot, a first bladder in the first cuff for placement in contiguous relationship to the arch, a second cuff for encircling the leg of the patient, a plurality of sequentially ascending second bladders in the second cuff for placement in contiguous relationship to the calf of the leg of the patient, a first conduit in communication with the first bladder, and second conduits in communication with the second bladders. The method of use includes the steps of applying pressure to a plurality of areas of the foot and leg in a cardiocepital direction while maintaining the pressure on a preceding area until after it has been applied to a succeeding area before releasing the pressure on the preceding area, and maintaining the pressure on the most cardiocepital area on the leg while applying pressure to the least cardiocepital area on the foot before releasing the pressure on the most cardiocepital area.

The Examiner concedes that Taheri et al. is "silent with regard to whether or not the fabric outer shell is inelastic or not," but argues that "clearly the fabric outer shell would have to be inelastic [for] if the fabric were elastic then the bladders would not bulge inwardly and would 'destroy the Taheri reference.'" This argument is without merit. Even if the outer shell of Taheri were made of rubber, it would still bulge inwardly, though to a lesser degree. Indeed, this is one of the shortcomings of the prior art which Appellants seek to overcome.

Conceding that the cloth fabric outer shell of Taheri might not be inelastic, the Examiner takes the alternative position that it would be obvious to modify Taheri "to provide good pressure against the deep veins." However, in rejecting claims under 35 U.S.C. §103, the Examiner must provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art to arrive at Appellants' claimed invention. There must be something *in the prior art* that suggests the proposed modification, other than the hindsight gained from knowledge that the inventor choose to combine these particular things in this particular way. Uniroyal Inc. v. Rudkin-

Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). In this case, however, there is absolutely no teaching or suggestion *from the prior art* regarding the Examiner's proposed modification. Accordingly, obviousness is precluded.

Group II - Claims 22 and 43, which stand or fall together

The claims of this group stand rejected under 35 U.S.C. §103(a) over Taheri et al., U.S. Patent No. 4,941,458. These claims add to respective independent claims the limitation of a controller operative to vary the level of compression as a function of time. As with various other dependent claims, the Examiner has rejected the claims of this group, stating that they "merely recite details of timing and intended use." However, it is the purpose of dependent claims to "recite details."

The "intended use" to which the Examiner is referring includes positive limitations that must be duly considered. In the *opinion of the Examiner*, "clearly the programmable operation of the pulse generator is capable of being programmed to perform whatever desired time intervals [sic] desired." However, the Examiner draws upon no substantive evidence to reach such conclusions.

According to the Examiner, "the only difference between the claimed invention and Taheri is the exact timing or operation of inflation of the bladders." Even if that were true, which it is not, such improvements *in and of themselves* should be at least considered in terms of patentability. The Examiner's statement that "there are no structural differences between the claims and the Taheri device" is simply without merit. Among other procedural mandates, the Examiner was reminded of 35 U.S.C. §112, last paragraph, which states that:

"An element in a claim for a combination may be expressed as a means or step for performing a specified function *without the recital of structure*, material, or acts in support thereof, and such claims shall be construed to cover the corresponding structure, material, or acts described in the specifications and equivalents thereof." (Emphasis added)

Since the Examiner has failed to produce a reference relevant to the rejection of the claims of this group, they are allowable.

Group III - Claims 23, 44 and 48 which stand or fall together

The claims of this group stand rejected under 35 U.S.C. §103(a) over Taheri et al., U.S. Patent No. 4,941,458. These claims include the limitation of a controller operative to vary the onset of decompression as a function of time. Since the Examiner has failed to produce a reference relevant to the rejection of the claims of this group, they are allowable.

Group IV - Claims 24, 38-49, which stand or fall together

The claims of this group stand rejected under 35 U.S.C. §103(a) over Taheri et al., U.S. Patent No. 4,941,458. These claims of this group are directed to a controller operative to reduce the rate of cycling between compression and decompression as a function of time. Since the Examiner has failed to produce a reference relevant to the rejection of the claims of this group, they are allowable.

Group V - Claims 25 and 39, which stand or fall together

The claims of this group stand rejected under 35 U.S.C. §103(a) over Taheri et al., U.S. Patent No. 4,941,458. These claims of this group add to their respective claims the limitation of a reduction in cycling between compression and decompression that drops off slowly over the course of several days. Since the Examiner has failed to produce a reference relevant to the rejection of the claims of this group, they are allowable.

Group VI - Claims 26 and 40, which stand or fall together

The claims of this group stand rejected under 35 U.S.C. §103(a) over Taheri et al., U.S. Patent No. 4,941,458. These claims of this group add to their respective claims the limitation that the rate of cycling between compression and decompression gradually reduces to one cycle every several minutes. Since the Examiner has failed to produce a reference relevant to the rejection of the claims of this group, they are allowable.

Group VII - Claims 27 and 41, which stand or fall together

The claims of this group stand rejected under 35 U.S.C. §103(a) over Taheri et al., U.S. Patent No. 4,941,458. These claims of this group add to their respective claims the limitation that the rate of

cycling between compression and decompression gradually reduces to one cycle every hour or longer. Since the Examiner has failed to produce a reference relevant to the rejection of the claims of this group, they are allowable.

Group VIII - Claims 28, 42 and 50, which stand or fall together

The claims of this group stand rejected under 35 U.S.C. §103(a) over Taheri et al., U.S. Patent No. 4,941,458. These claims of this group add to their respective claims the limitation of a user operable control for switching between a fixed rate of compression and decompression to an automatic mode wherein the cycling between compression and decompression reduces over time. Since the Examiner has failed to produce a reference relevant to the rejection of the claims of this group, they are allowable.

Group IX - Claims 29-30, which stand or fall together

Claims 29 and 30 stand rejected under 35 U.S.C. §103(a) over Taheri, U.S. Patent No. 4,941,458, in view of Tumey, U.S. Patent No. 5,769,801. Claim 29 adds to claim 21 the limitation of a pressure sensor in pneumatic communication with the bladder to terminate the operation of a compressor upon reaching a desired level of positive pressure. The Examiner apparently concedes that Taheri is silent with regard to the use of a pressure sensor, but combines Tumey et al. '801 with Taheri et al. '458 *with no teaching or suggestion to do so from the prior art*. In rejecting claims under 35 U.S.C. §103, the Examiner must provide a reason why one having ordinary skill in the pertinent art would have been led to combine references so as to arrive at Applicant's claimed invention. There must be something *in the prior art* that suggests the combination, other than the hindsight gained from knowledge that the inventor choose to combine these particular things in this particular way. Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). The Examiner is also required to make specific findings on a suggestion to combine prior art references. In Re Dembeczak, 175 F.3d 994, 1000-01, 50 USPQ2d 1614, 1617-19 (Fed. Cir. 1999). Since the Examiner has failed to provide a reason why one having ordinary skill in the pertinent art would have been led to combine the cited references so as to arrive at Applicant's claimed invention, the claims of this group are allowable.

Group X - Claim 31

Claim 31 stands rejected under 35 U.S.C. §103(a) over Taheri, U.S. Patent No. 4,941,458, in view of Vinmont, U.S. Patent No. 3,908,642. Claim 31 adds to claim 21 the limitation that the substantially inelastic outer shell forms part of a cast. Even though the Examiner had previously argued that the fabric of Taheri is substantially inelastic, the Examiner combines Taheri and Vinmont, the latter teaching the use of a cast for an entirely different purpose. The Examiner states that "it would have been obvious to one of ordinary skill in the art to modify Taheri to use it in combination with a cast as taught by Vinmont since the art of improving cardiocepital venous flow applies to people in casts who are likewise ambulatory as well as taught by Vinmont." Since the Examiner offers no support for conclusions regarding the "art of improving cardiocepital venous flow" this claim is allowable.

Group XI - Claim 35

Claim 35 stands rejected under 35 U.S.C. §103(a) over Taheri, U.S. Patent No. 4,941,458, in view of Corcoran, U.S. Patent No. 2,880,721. Claim 35 adds to claim 21 the limitation that the substantially inelastic outer shell is dimensioned for wearing around at least a portion of the human hand. Since Taheri is "clearly" directed to "aiding cardiocepital venous flow from the foot and leg of an ambulatory patient" (see U.S. Patent No. 4,941,458 title), the Examiner attempts to combine another reference, namely that of Corcoran, which resides in a hand or foot carried pulsating massaging device. The Examiner states that this combination would have been obvious "for those people who need to stimulation [sic] of those limb extremities." According to this reasoning, then, whatever body part Appellants' might mention, it would be obvious in view of the Examiner's opinion. Examiner has failed to provide a reason why one having ordinary skill in the pertinent art would have been led to combine the cited references so as to arrive at Applicant's claimed invention, this claim is allowable.

Group XII - Claim 36

Claim 36 unpatentable under 35 U.S.C. §103(a) over Taheri, U.S. Patent No. 4,941,458, in view of Johnson, Jr. et al., U.S. Patent No. 5,496,262. Claim 36 adds to claim 21 that the substantially inelastic outer is substantially rigid. Again, given that Taheri contains no such

teaching or disclosure, the Examiner attempts to combine the teachings of Johnson, Jr. ('262) on the grounds that "to use a rigid outer shell as taught by Johnson as obvious equivalent alternative [sic] for the cuff." There is simply no support or justification for these or the other combinations suggested herein. Accordingly, this claim is allowable.

Group XIII – Claim 48

Claim 48 stands rejected under 35 U.S.C. §103(a) over Taheri et al., U.S. Patent No. 4,941,458. This claim includes, among other limitations, a controller operative to "vary the onset of decompression as a function of time."

Conclusion

Appellant submits that the claims define patentable subject matter and are in condition for allowance. Such action is respectfully requested.

Respectfully submitted,


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APPENDIX A
CLAIMS ON APPEAL

21. Portable apparatus for deep vein thrombosis (DVT) prophylaxis, comprising:
 - a substantially inelastic outer shell having an inner wall, the shell being dimensioned for wearing around a portion of a human limb;
 - an inflatable/deflatable bladder supported between the inner wall of the outer shell and the portion of a human limb; and
 - battery-operated electrical and pneumatic circuitry, all wearable by the user without interconnection to any other apparatus, the electrical circuitry including:
 - an electrically operated air compressor, and
 - a controller operative to inflate the bladder on periodic basis so as to create a level of compression against the portion of the limb for a period of time, after which the bladder deflates until the next compression cycle.
22. The apparatus of claim 21, wherein the controller is operative to vary the level of compression as a function of time.
23. The apparatus of claim 21, wherein the controller is operative to vary the onset of decompression as a function of time.
24. The apparatus of claim 21, wherein the controller is operative to reduce the rate of cycling between compression and decompression as a function of time.
25. The apparatus of claim 24, wherein the reduction in cycling between compression and decompression drops off slowly over the course of several days.
26. The apparatus of claim 25, wherein the rate of cycling between compression and decompression gradually reduces to one cycle every several minutes.

27. The apparatus of claim 25, wherein the rate of cycling between compression and decompression gradually reduces to one cycle every hour or longer.

28. The apparatus of claim 21, further including a user operable control for switching between a fixed rate of compression and decompression to an automatic mode wherein the cycling between compression and decompression reduces over time.

29. The apparatus of claim 21, further including a pressure sensor in pneumatic communication with the bladder to terminate the operation of the compressor upon reaching a desired level of positive pressure.

30. The apparatus of claim 29, further including a valve for deflating the bladder upon achieving a predetermined pressure.

31. The apparatus of claim 21, wherein the substantially inelastic outer shell forms part of a cast.

32. The apparatus of claim 21, wherein the substantially inelastic outer shell is dimensioned for wearing around an upper portion of a human calf.

33. The apparatus of claim 21, wherein the substantially inelastic outer shell is dimensioned for wearing around a lower portion of the human calf immediately above a human foot.

34. The apparatus of claim 21, wherein the substantially inelastic outer shell is dimensioned for wearing at least a portion of a human foot.

35. The apparatus of claim 21, wherein the substantially inelastic outer shell is dimensioned for wearing around at least a portion of a human hand.

36. The apparatus of claim 21, wherein the substantially inelastic outer shell is substantially rigid.

37. The apparatus of claim 21, wherein the substantially inelastic outer shell is composed of a non-stretch fabric.

38. Portable apparatus for deep vein thrombosis (DVT) prophylaxis, comprising:
a substantially inelastic outer shell having an inner wall, the shell being dimensioned for wearing around a portion of a human limb;

an inflatable/deflatable bladder supported between the inner wall of the outer shell and the portion of a human limb; and

battery-operated electrical and pneumatic circuitry, all wearable by the user without interconnection to any other apparatus, the electrical circuitry including:

an electrically operated air compressor, and

a controller operative to perform the following functions:

a) inflate the bladder on periodic basis so as to create a level of compression against the portion of the limb for a period of time, after which the bladder deflates until the next compression cycle, and

b) reduce the rate of cycling between compression and decompression as a function of time.

39. The apparatus of claim 38, wherein the reduction in cycling between compression and decompression gradually reduces over the course of several days.

40. The apparatus of claim 39, wherein the rate of cycling gradually reduces to one cycle every several minutes.

41. The apparatus of claim 39, wherein the rate of cycling gradually reduces to one cycle every hour or longer.

42. The apparatus of claim 38, further including a user operable control for switching between a fixed rate of compression and decompression to an automatic mode wherein the cycling between compression and decompression reduces over time.

43. The apparatus of claim 38, wherein the controller is further operative to vary the level of compression as a function of time.

44. The apparatus of claim 38, wherein the controller is further operative to vary the onset of decompression as a function of time.

45. Portable apparatus for deep vein thrombosis (DVT) prophylaxis, comprising:

a substantially inelastic outer shell having an inner wall, the shell being dimensioned for wearing around a portion of a human limb;

an inflatable/deflatable bladder supported between the inner wall of the outer shell and the portion of a human limb; and

battery-operated electrical and pneumatic circuitry, all wearable by the user without interconnection to any other apparatus, the electrical circuitry including:

an electrically operated air compressor, and

a controller operative to perform the following functions:

a) inflate the bladder on periodic basis so as to create a level of compression against the portion of the limb for a period of time, after which the bladder deflates until the next compression cycle, and

b) vary the level of compression as a function of time.

46. The apparatus of claim 45, wherein the controller is further operative to reduce the rate of cycling between compression and decompression as a function of time.

47. The apparatus of claim 45, further including a user operable control for switching between a fixed rate of compression and decompression to an automatic mode wherein the cycling between compression and decompression reduces over time.

48. Portable apparatus for deep vein thrombosis (DVT) prophylaxis, comprising:
 - a substantially inelastic outer shell having an inner wall, the shell being dimensioned for wearing around a portion of a human limb;
 - an inflatable/deflatable bladder supported between the inner wall of the outer shell and the portion of a human limb; and
 - battery-operated electrical and pneumatic circuitry, all wearable by the user without interconnection to any other apparatus, the electrical circuitry including:
 - an electrically operated air compressor, and
 - a controller operative to perform the following functions:
 - a) inflate the bladder on periodic basis so as to create a level of compression against the portion of the limb for a period of time, after which the bladder deflates until the next compression cycle, and
 - b) vary the onset of decompression as a function of time.
49. The apparatus of claim 48, wherein the controller is further operative to reduce the rate of cycling between compression and decompression as a function of time.
50. The apparatus of claim 48, further including a user operable control for switching between a fixed rate of compression and decompression to an automatic mode wherein the cycling between compression and decompression reduces over time.